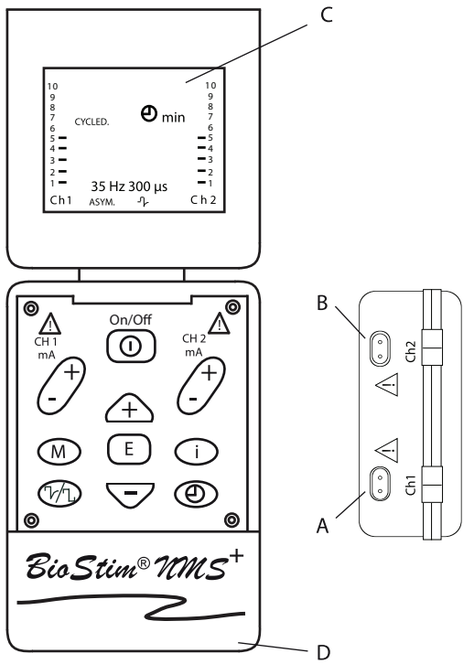


Accessories: 2 Lead Wires with electrodes
1 Instruction Booklet
4 AA Batteries
1 Carry Pouch

Only use accessories, electrodes, leadwires and batteries approved by BioMedical Life Systems, Inc.

Technical Data

Dimensions	3.9" x 2.6" x 1.3" (99mm x 65mm x 33 mm)
Weight	8 oz (226 grams)
Power supply	4 AA Batteries, type LR6
Channels	Dual
Waveform	Symmetrical, biphasic, square Asymmetrical, biphasic, square
Pulse Rate	Adjustable 1-120 Hz. A Pulse Rate of less than 60 Hz should be used if repeated muscle contractions are desired. A Pulse Rate of at least 10 Hz should be used if forceful, tetanic muscle contractions are desired.
Pulse Width	Adjustable 50-400 uS
Ramp on	0-10 seconds
On time	0-99 seconds

Technical Data

Ramp off	0-10 seconds
Off time	0-99 seconds
Delay	0-99 seconds
Mode Selection	**1.Constant:** Use the Constant Mode or a Pulse Rate greater than 60 Hz. for the relaxation of muscle spasms only. Use of continuous stimulation and/or rates above the normal physiological range (e.g., greater than 60 Hz) could lead to rapid onset of muscle fatigue, making the device less effective in producing repeated forceful muscle contractions. 2.**Cycled** 3.**Reciprocating**

Four additional fixed Cycled programs are offered:

Therapy 1 - 35 Hz, 400 µs, Symmetrical Biphasic,
Therapy 2 - 35 Hz, 400µs, Asymmetrical Biphasic
Therapy 3 - 50 Hz, 180µs, Symmetrical Biphasic
Therapy 4 - 20 Hz, 250µs, Symmetrical Biphasic

One additional fixed Constant program is offered:

Therapy 5 - 10 Hz, 50µs, Symmetrical Biphasic

(Data was recorded across a 500 OHM resistance load)

Intensity	Continuously adjustable from 0-120 mA peak(0-60V)
Output Voltage	0-60 Volts peak to peak
Tolerance	+/- 1 %

BioStim NMS + Button Descriptions and Functional Sequences

Button Symbol	Button Function
M	MODE SELECT
i	SETTING INFORMATION KEY
PR/PW	PULSE RATE/PULSE WIDTH & WAVEFORM SELECT
◴	TIMER KEY
▲ ▼	INCREASE VALUE/ DECREASE VALUE
+ −	AMPLITUDE CONTROL
E	ENTER
⏻	ON/OFF

Graphic Symbol Definitions

Refer to operating instructions

An IEC 601-1 safety standard (type BF)

CE 0086 We herewith declare that the above mentioned product meets the provisions of the Medical Device Directive

Patient Safety Information

Precautions should be taken when stimulation is used;

- After recent surgical procedure where muscle contraction may disrupt the healing process.
- After an acute trauma or fracture where there is a tendency to hemorrhage.
- Over the menstruating uterus.
- Where the sensory nerve damage has caused the loss of normal skin sensation.

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

Caution:

NMS or EMS Devices should only be used under medical supervision fo r adjunctive therapy in the treatment of medical diseases and conditions. Dependent upon government regulation, this device may or may not require a medical prescription.

Federal law (USA) restricts the sale by, or on the order of, a physician so licensed by the State. Keep out of reach of children.

Adverse Reactions:

Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternative conductive medium, or alternate electrode placement. Improper use of stimulation may result in skin irritation and burns beneath the electrodes. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

Indications:

External electrical neuromuscular stimulation using bi-phasic output is indicated as therapeutic adjunct for prevention or retardation of muscle disuse atrophy; relaxation of muscle spasm; muscle reeducation; maintaining and increasing the range of motion; increasing local blood circulation and as an immediate post surgical stimulation of calf muscles to prevent venous thrombosis.

Contraindications:

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers. NMS or

EMS devices should not be applied over, or in proximity to, cancerous lesions. NMS devices should not be used while driving, operating machinery or during any other activity in which involuntary muscle contraction may put the user at undue risk of injury. Stimulation should not be applied over the carotid sinus.

Severe spasm of the laryngeal and/or pharyngeal muscles may occur when electrodes are placed over the neck or mouth. (These contractions may be strong enough to close the airway or cause difficulty in breathing.) Stimulation should not be applied transcerebrally.

Adequate precaution should be taken when treating patients with suspected heart problems or epilepsy.

Caution should be exercised in the transthoracic application of EMS devices so that the introduction of electrical current into the heart does not cause arrhythmias. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

Persistent use of stimulation in the presence of skin irritation may be injurious.

The safety of electrical stimulation for use during pregnancy has not been established. The long-term effects of chronic electrical stimulation are unknown.

EMS devices should be kept out of the reach of children.

Simultaneous connection to RF surgery equipment can cause a burn. Operation near (e.g. 1m) short wave or micro wave therapy equipment can change the output values of the stimulator.

This equipment may be effected by electromagnetic interference. Also, other electrical equipment in close vicinity may be effected by the BioStim®NMS +. If such effects are suspected either switch off the offending equipment or increase the distance between the effected equipment and that suspected of causing the interference, or shorten connecting leads.

Introduction to Muscle Stimulation

Electrical Muscle Stimulation (EMS) or NeuroMuscular Stimulation (NMS) is the use of electrical stimulation on muscle groups to contract and reeducate muscles. Some of the uses of EMS are as follows:

1. The Prevention or Retardation of Muscle Disuse Atrophy: Muscle disuse atrophy is a reduction in muscle contraction and size due to prolonged impairment or joint immobility from surgery or injury. The use of electrical stimulation to contract the muscles assists in prevention of disuse atrophy.

2. Relaxation of Muscle Spasms: Muscle spasms often occur in areas of localized pain and tenderness. Stimulation is used to fatigue the spasmodic muscle.

3. Maintaining and Increasing Range of Motion

4. Muscle Reeducation
5. Increasing Local Blood Circulation
Rhythmic muscle contraction helps improve local blood circulation.
6. Immediate Postsurgical Stimulation of Calf Muscles to Prevent Venous Thrombosis. The use of NMS or EMS to increase local blood circulation assists in the prevention of venous thrombosis.

Programming Instructions

Many of the BioStim® NMS + settings are already programmed into the device. To accept the data push the **ENTER E** (6) key. To change different parameters, certain Key Pad Buttons are used.
Each press of the button will scroll you through different parameters to choose from. By pressing the + (4) or - (9) you can increase or decrease the values of the parameters. Pressing the **E** (6) will accept the value. The following Key Pad Buttons will allow you to scroll through different parameters.
PW/PR (8): **SYM** (Symmetrical Biphasic Waveform) **ASYM** (Asymmetrical Biphasic Waveform) **PR** (Pulse Rate Value) **PW** (Pulse Width Value).
M (5): **CONST** (Constant Stimulation) **CYCLED** (Cycled Stimulation)**RECIPR** (Reciprocating Stimulation) **THERAPY 1, THERAPY 2, THERAPY 3, THERAPY 4, and THERAPY 5.** (See Programmed Therapy Section for parameter settings).
Clock Symbol (10): Minutes of Therapy

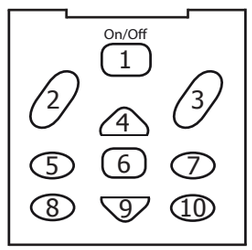
CONSTANT Stimulation

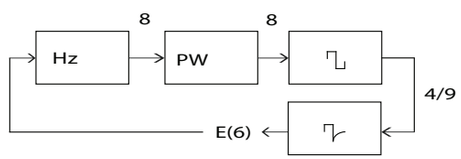
- Attach leadwires to Channel 1 (CH1) and if needed to Channel 2 (CH2). (A and B)
- Attach electrodes to leadwires following instructions on electrode packaging.
- Attach electrodes to body.
- Turn on the device and press (1)
- The last settings entered are displayed. To increase or decrease the intensity press + (4) or - (9). To accept the parameters press (6).

Changing PR, PW or Waveform

- Press (8) PR (Hz) will begin to blink. To change the value press +(4) or - (9). To save the setting press **E** (6).

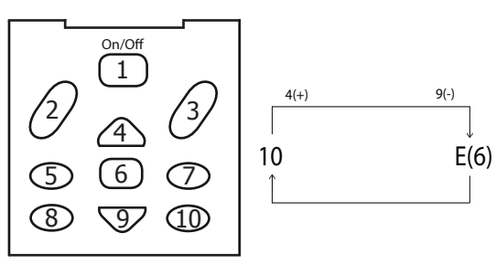
- To change PW (µs) press (8) again, to change the value press + (4) or -(9) to increase/decrease the value followed by pressing **E** (6) to save.
- To move to next setting, Waveform, press (8), to select given Waveform press E (6). To change the Waveform press (4) or (9) and then **E** (6) to select
- Increase the Intensity Buttons (2 and 3) to begin therapy.





Setting the Patient Timer

- To set the Patient Timer, press (10) and the +(4) or -(9) to increase or decrease the minutes. Once you have selected the value press **ENTER (6)**
- Increase the Intensity Buttons (2 and 3) to begin therapy.

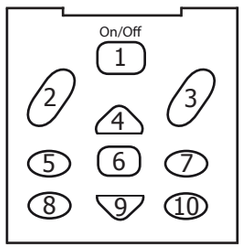


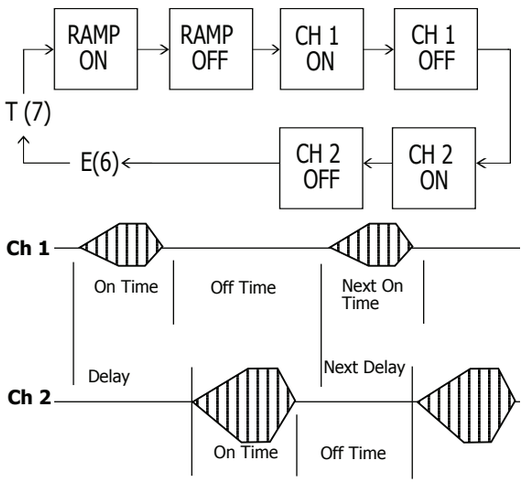
CYCLED Stimulation

- Attach leadwires to Channel 1 (CH1) and if needed to Channel 2 (CH2). (A and B)
- Attach electrodes to leadwires following instructions on electrode packaging
- Turn on the device press (1)
- Press M (5) until Cycled begins to blink. Press E to step through each value and to accept the each pre-programmed parameter. To increase the intensity Press buttons (2 and 3).

	Channel 1	Channel 2
Ramp on	2.0 sec.	2.0 sec.
Ramp off	2.0 sec.	2.0 sec.
On time	4.0 sec.	4.0 sec.
Off time	30 sec.	30 sec.
Delay		0.0 sec

At any point press E(6) to accept the given timing parameter and step to the next setting. Or to change the value, press +(4) or -(9) to increase/decrease the parameter, followed by E(6) to save.





CYCLED Stimulation (cont.)

To change any of the timing features press i (7). RAMP ON "xx" sec is displayed. This value represents the RAMP ON time for both Channels 1 and 2.
The RAMP ON value can be increased or decreased using the + (4) and - (9) buttons. Once the selected time has been chosen, press E (6) to save. Now, RAMP OFF and "2 sec." appears on the screen. This value represents the RAMP OFF time for both Channel 1 and 2.
The RAMP OFF value can be increased or decreased using the +(4) and- (9) buttons. Accept the value by pressing E (6) to save.
When CH 1 ON is initially displayed, the value shown is equal to the sum of the RAMP ON and RAMP OFF times. At this point, add the number of the desired contraction time to the given value. (i.e. RAMP ON + RAMP OFF + ON TIME = TOTAL ON TIME. If the RAMP ON and RAMP OFF are each set at the default of 2 seconds, the ON TIME display will initially read "4". If the actual contraction time desired is 10 seconds, 10 must be added to the ON TIME and the display will read "14" seconds.)
Use the + (4) to set the contraction time and press E (6) to save.
CH 1 OFF is now displayed and represents the total amount of time CH 1 will be off. Accept the value by pressing E (6) or use the + (4) and - (9) buttons to change the value. Press E (6) to save.
Follow the instructions above to set CH 2 values to read exactly the same as the CH 1 values. The only exception would be when the DELAY is used.
The value set for the DELAY must also be added to CH 1 OFF TIME.
When CH 2 DELAY is displayed. CH 2 can be delayed 1-99 seconds. Accept this value by pressing E (6) or use the +/- (4 and 9) buttons to change the value. Press E (6) to save.
Note the following example showing a DELAY of 2 seconds:

	Channel 1	Channel 2
Ramp on	2.0 sec.	2.0 sec.
Ramp off	2.0 sec.	2.0 sec.
On time	4.0 sec.	4.0 sec.
Off time	32 sec.	30 sec.
Delay		2.0 sec

The CYCLED now has been timed and stops flashing. You can still change the PR, PW or Waveform (please see Changing PR, PW or Waveform) or set the Patient Timer (please see Setting the Patient Timer).
The total of Ch1 ON TIME and Ch1 OFF TIME must equal the total of Ch2 ON TIME plus Ch2 OFF TIME plus Ch2 DELAY TIME. If the totals are not equal, "Err!" will be displayed.
Increase the Intensity Buttons (2 and 3) to begin therapy.

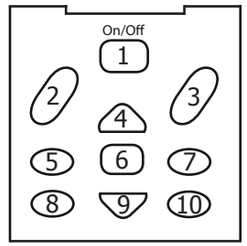
RECIPROCATING Stimulation

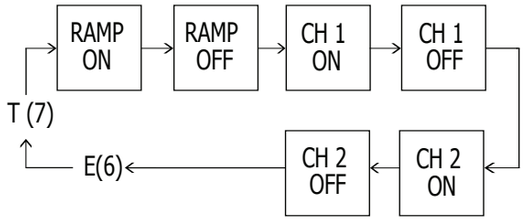
- Attach leadwires to Channel 1 (Ch 1) and if needed to Channel 2 (Ch 2). (A and B)
- Attach electrodes to leadwires following instructions on electrode packaging.
- Place electrodes to the body
- Turn on the device (1)
- Press M (5) until RECIPR begins to blink. Press E(6) to step through each value and to accept each pre-programmed value.

35 Hz, 300 uS, Symmetrical Biphasic Square Waveform
Press (i) once to display timing features.
To increase or decrease the parameters press + (4) or -(9). To accept the value press (E) to save. Once the parameter is saved, the next parameter will be displayed.
Pressing the (i) or (E) keys will scroll through the parameters in the following order:

Ramp on	2.0 sec.
Ramp off	2.0 sec.
Channel 1 on	4.0 sec.
Channel 1 off	30 sec.
Channel 2 on	4.0 sec.
Channel 2 off	30 sec.

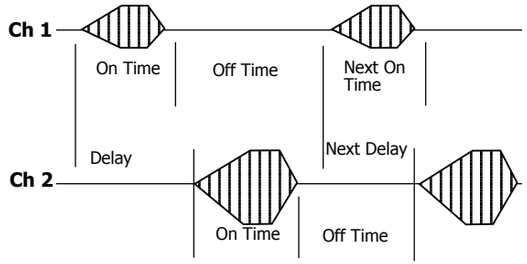
At any point press E(6) to accept the given timing parameter and step to the next setting. Or to change the value, press +(4) or -(9) to increase/decrease the parameter, followed by E(6) to save.





To calculate the actual duration of the contraction, you must subtract the RAMP ON and RAMP OFF times from the ON TIME.

The RECIPR now has been timed and stops flashing. You can still change the PR, PW or Waveform (please see Changing PR, PW or Waveform) or set the Patient Timer (please see Setting the Patient Timer).
Increase the Intensity Buttons (2) and (3) to begin therapy.



Pre-Programmed Therapy

There are five pre-programmed therapies to choose from in the BioStim NMS +. These therapies are "fixed" and cannot be altered.

- Turn on the device press (1)
- Press M (5) to scroll through the different Mode Selections; CONST., CYCLED, RECIPR. THERAPY1, THERAPY 2, THERAPY 3, THERAPY 4, and THERAPY 5. To accept any of the following pre-programmed therapies increase the Intensity Button (2 and 3) when the screen displays that particular therapy you want to use. Below are the parameters for each Therapy.

Therapy 1 (Cycled)
35 Hz, 400 uS, Symmetrical Biphasic Waveform

	Channel 1	Channel 2
Ramp on	2.0 sec.	2.0 sec.
Ramp off	2.0 sec.	2.0 sec.
On time	10 sec.	10 sec.
Off time	30 sec.	30 sec.
Delay	0 sec.	0 sec.

Therapy 2 (Cycled)
35 Hz, 400 uS, Asymmetrical Biphasic Square Waveform

	Channel 1	Channel 2
Ramp on	2.0 sec.	2.0 sec.
Ramp off	2.0 sec.	2.0 sec.
On time	10 sec.	10 sec.
Off time	30 sec.	30 sec.
Delay	0 sec.	0 sec.

Therapy 3 (Cycled)
50 Hz, 180 uS, Symmetrical Biphasic Square Waveform

	Channel 1	Channel 2
Ramp on	2.0 sec.	2.0 sec.
Ramp off	2.0 sec.	2.0 sec.
On time	10 sec.	10 sec.
Off time	20 sec.	20 sec.
Delay	0 sec.	0 sec.

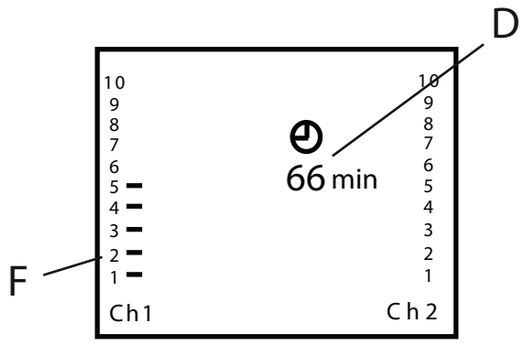
Therapy 4 (Cycled)
20 Hz, 250 uS, Symmetrical Biphasic Square Waveform

	Channel 1	Channel 2
Ramp on	2.0 sec.	2.0 sec.
Ramp off	2.0 sec.	2.0 sec.
On time	5 sec.	5 sec.
Off time	10 sec.	10 sec.
Delay	0 sec.	0 sec.

Therapy 5 (Constant)
10 Hz, 50 uS, Symmetrical Biphasic Square Waveform

Patient Compliance Meter

When turning off the Patient Lock feature, the amount of time the Patient has used the device is displayed. Below the Clock Symbol (D) the number of hours the device has been used will be displayed. Once 99 hours has been reached, a bar next to the "1" on the left Amplitude Display (F) will appear. Each bar indicates 100 hours of use. The maximum amount of time that will be displayed is 1099 hours. The diagram (below) indicates the device has been used for 566 hours. To delete the stored time, press and hold both Channel Amplitudes (2) and (3) simultaneously in the "-" position.



Parameter or Patient Lock

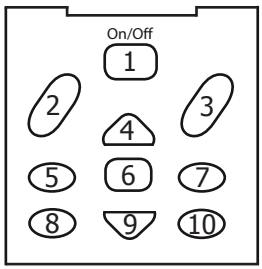
The BioStim® NMS+ has a Patient or Parameter Lock Feature. When "turned on", this feature only allows the Patient to adjust the Intensity Controls and Timer. No other parameters; mode (constant, cycled, reciprocating, therapy 1-5), Timing, Ramp On, Ramp Off, On Time, Off Time, Delay, Waveform (symmetrical or asymmetrical), Pulse Rate and Pulse Width can be altered or changed by the Patient.

To Turn On the Patient Lock Feature

After the desired treatment parameters have been selected (see Programming Instructions) press ENTER E (6) and the + (4) simultaneously. Hold the buttons until you see the Clock symbol flash. The Patient Lock Feature is now activated.

To Turn Off the Patient Lock Feature

Press the ENTER E (6) and the -(9) simultaneously. Hold the buttons until you see the Clock symbol stop flashing. The Patient Lock Feature is now deactivated.



Batteries

In order to maintain the functional operation of the BioStim® NMS + ,the batteries will have to be changed periodically. The device is supplied with 4 AA Alkaline batteries.

When batteries are running low, a battery image will appear and flash on the bottom right hand corner of the display screen (C). When this image appears, the batteries should be changed to ensure maximum performance.

Warning: We do not recommend the use of rechargeable batteries, as they may weaken the performance and/or readout of the device.

To change batteries:

- Before opening the battery compartment, check to make sure that the device is switched off.
- Flip open the battery compartment cover.

- Remove the batteries from the compartment. Gently insert the new batteries by matching the +/– end of each battery with the +/– symbol found inside the battery compartment.
- Flip the battery cover to the closed position.
- Remove the batteries if you do not plan to use the device for long periods of time. Otherwise leakage and damage to the device may occur.
- Dispose of batteries in a proper manner.

Safety and Technical Checks

Once a year, a maintenance check should be performed on the device as follows:

- Visually check the exterior case of the device for damage.
- Visually check the input and output sockets for damage.
- Visually check the device for clarity of reading instructions and indicator decals.
- Visually check that the symbols of the LCD are operating correctly.
- Visually check the leadwires and electrodes for damage

Malfunctions

Should any malfunctions occur while using this device, check:

- Whether the leadwires and electrodes are correctly connected to the device. The leadwires should be inserted firmly into the device sockets.
- For possible damage to the leadwires. Change the leadwires if any damage is detected.

Do not attempt to repair a device yourself!

Opening the device case voids the warranty. Please contact the dealer from whom the device was purchased. If they are unable to assist you, please contact:

In the USA and Canada, BioMedical Life Systems, Inc., (760) 727-5600.

In Europe, BMLS BV, Alkmaar, The Netherlands.

This device MUST only be serviced by the manufacturer.

To reorder any accessories or supplies, contact your dealer.

Maintenance and Care

- The case housing is made of insulated ABS plastic and can be cleaned with isopropyl alcohol.